

EC Design Examination Certificate: Certificate JP20/819943405

CREATE MEDIC CO., LTD.

2-5-25 Chigasakiminami, Tsuzuki-ku, Yokohama, Kanagawa,
224-0037 Japan

Device Identification:

Sterile vascular catheter

Micro Catheter (Portier II) 1.8Fr / 2.8Fr, Micro Catheter (Mirabeau II)
2.1Fr / 2.9Fr, Micro Catheter (Rivage) 2.6Fr / 2.9Fr.

Intended Purpose of Device:

Inserting percutaneously intravascularly and injecting a contrast medium into a vascular site, injecting a drug in intra-arterial therapy and injecting an embolic substance in embolisation procedures (not for neurological use or for use in children).

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 22 October 2020 until 24 May 2024

Issue 2. Certified since 26 June 2020

and first certified by SGS Belgium NV since 26 June 2020

Certification is based on reports numbered JP/YOK 14476 dated 30 March 2020

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
14 September 2020	Change to certificate wording

Authorised by

SGS Belgium NV, Notified Body 1639

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